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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,625	07/16/2001	Peter Kufer	07258-023001	3114

7590 11/18/2003

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EXAMINER	
YU, MISOOK	

ART UNIT	PAPER NUMBER
1642	14

DATE MAILED: 11/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/744,625	KUFER ET AL.	
	Examiner	Art Unit	
	MISOOK YU, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 August 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-41* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The restriction requirement mailed on 09-30-2002 is vacated and replaced with this restriction requirement.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Claims 1-5, 19-23, and 26 link(s) inventions 1-42. Claim 1-7, 11 link inventions 1-9; claims 8 links inventions 10-13, claims 12-14 links inventions 15-20, claims 12-13, and 15 links inventions 21-39. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s). Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C.

121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32

(CCPA 1971). See also MPEP § 804.01.

Group 1, claim(s) 1-7, 11, 26, and 19-23, drawn to a multifunctional compound comprising B7-1, a cell surface molecule of fragment thereof of a T-cell co-stimulatory ligand.

Group 2, claim(s) 1-7, 11, 26, and 19-23, drawn to a multifunctional compound comprising B7-2, a cell surface molecule of fragment thereof of a T-cell co-stimulatory ligand.

Group 3, claim(s) 1-7, 11, 26, and 19-23, drawn to a multifunctional compound comprising ICAM-1, a cell surface molecule of fragment thereof of a T-cell co-stimulatory ligand.

Group 4, claim(s) 1-7, 11, 26, and 19-23, drawn to a multifunctional compound comprising ICAM-2, a cell surface molecule of fragment thereof of a T-cell co-stimulatory ligand.

Group 5, claim(s) 1-7, 11, 26, and 19-23, drawn to a multifunctional compound comprising ICAM-3, a cell surface molecule of fragment thereof of a T-cell co-stimulatory ligand.

Group 6, claim(s) 1-7, 11, 26, and 19-23, drawn to a multifunctional compound comprising LFA-3, a cell surface molecule of fragment thereof of a T-cell co-stimulatory ligand.

Group 7, claim(s) 1-7, 11, 26, and 19-23, drawn to a multifunctional compound comprising CD137, a cell surface molecule of fragment thereof of a T-cell co-stimulatory ligand.

Group 8, claim(s) 1-7, 26, and 19-23, drawn to a multifunctional compound comprising an antigen binding region specific for a tumor associated antigen.

Group 9, claim(s) 1-7, 19-23, 33-34, 40, 26, and 41, drawn to a multifunctional compound, kit, composition comprising a proteinaceous compound capable of providing providing the primary activation signal for T-cells.

Group 10, claim(s) 1-6, 8, 26, and 19-23, drawn to a multifunctional compound comprising V_H and V_L regions of the murine anti-human 17-1A antibody M79 as scFV fragment or said functional part thereof

Group 11, claim(s) 1-6, 8, 26, and 19-23, drawn to a multifunctional compound comprising V_H and V_L regions of anti-Lewis Y antibody as scFV fragment or said functional part thereof.

Group 12, claim(s) 1-6, 8, 26 and 19-23, drawn to a multifunctional compound comprising V_H and V_L regions of anti-CD3 antibody TR66 as scFV fragment or said functional part thereof.

Group 13, claim(s) 1-6, 8, 26, and 19-23, drawn to a multifunctional compound comprising V_H and V_L regions of human anti-human EpCAM antibody as scFV fragment or said functional part thereof.

Group 14, claim(s) 1-5, 12-14, 26, and 19-23, drawn to a multifunctional compound comprising interleukins.

Group 15, claim(s) 1-5, 12-14, 26, and 19-23, drawn to a multifunctional compound comprising interferons.

Group 16, claim(s) 1-5, 12-14, 26, and 19-23, drawn to a multifunctional compound comprising GM-CSF.

Group 17, claim(s) 1-5, 12-14, 26, and 19-23, drawn to a multifunctional compound comprising G-CSF.

Group 18, claim(s) 1-5, 12-14, 26, and 19-23, drawn to a multifunctional compound comprising M-CSF.

Group 19, claim(s) 1-5, 12-14, 26, and 19-23, drawn to a multifunctional compound comprising TNFs.

Group 20, claim(s) 1-5, 12-14, 26, and 19-23, drawn to a multifunctional compound comprising VEGF.

Group 21, claim(s) 1-5, 12-13, 15, 26, and 19-23, drawn to a multifunctional compound comprising IL-8.

Group 22, claim(s) 1-5, 12-13, 15, 26, and 19-23, drawn to a multifunctional compound comprising Eotoxin.

Group 23, claim(s) 1-5, 12-13, 15, 26, and 19-23, drawn to a multifunctional compound comprising GRO alpha.

Group 24, claim(s) 1-5, 12-13, 15, 26, and 19-23, drawn to a multifunctional compound comprising GRO beta.

Group 25, claim(s) 1-5, 12-13, 15, 26, and 19-23, drawn to a multifunctional compound comprising GRO gamma.

Group 26, claim(s) 1-5, 12-13, 15, 26, and 19-23, drawn to a multifunctional compound comprising IP-10.

Group 27, claim(s) 1-5, 12-13, 15, 26, and 19-23, drawn to a multifunctional compound comprising MCP-1.

Group 28, claim(s) 1-5, 12-13, 15, 26, and 19-23, drawn to a multifunctional compound comprising MCP-2.

Group 29, claim(s) 1-5, 12-13, 15, 26, and 19-23, drawn to a multifunctional compound comprising MCP-3.

Group 30, claim(s) 1-5, 12-13, 15, 26, and 19-23, drawn to a multifunctional compound comprising MCP-4.

Group 31, claim(s) 1-5, 12-13, 15, 26, drawn to a multifunctional compound comprising MIG.

Group 32, claim(s) 1-5, 12-13, 15, 26, and 19-23, drawn to a multifunctional compound comprising MIP-1alpha.

Group 33, claim(s) 1-5, 12-13, 15, 26, and 19-23, drawn to a multifunctional compound comprising MIP-1beta.

Group 34, claim(s) 1-5, 12-13, 15, 26, and 19-23, drawn to a multifunctional compound comprising NAP-2.

Group 35, claim(s) 1-5, 12-13, 15, 26, and 19-23, drawn to a multifunctional compound comprising RANTES.

Group 36, claim(s) 1-5, 12-13, 15, 26, and 19-23, drawn to a multifunctional compound comprising 1309.

Group 37, claim(s) 1-5, 12-13, 15, 26, and 19-23, drawn to a multifunctional compound comprising NAP-2.

Group 38, claim(s) 1-5, 12-13, 15, 26, and 19-23, drawn to a multifunctional compound comprising Lymphotactin.

Group 39, claim(s) 1-5, 12-13, 15, 26 and 19-23, drawn to a multifunctional compound comprising SDF-1.

Group 40, claim(s) 1-5, 16, 19-23, 26, drawn to a multifunctional compound comprising Fas ligand or fragment thereof.

Group 41, claim(s) 1-5, 17, 19-23, 26, drawn to a multifunctional compound comprising growth factor or fragment thereof.

Group 40, claim(s) 1-5, 18, 19-23, 26 drawn to a multifunctional compound comprising angiogenesis inhibitor or fragment thereof.

Group 41, claim(s) 1-5, 19-26, drawn to a multifunctional compound comprising GM-CSF, IL-2 and ScFv fragment comprising VH and VI region of the human anti-human EpCAM antibody N-terminally linked to said constant CH1 or CL domains.

Group 42, claim(s) 1-5, 19-23, 26, 27, drawn to a multifunctional compound comprising functional domains derived from a non-immunoglobulin domain.

Groups 43-84, claims 28-35, 41 drawn to polynucleotide, vector, a mammalian host cell, method to produce each of the product in groups 1-42 above.

Groups 85-168, claims 36-39, drawn to method of using each of the products 1-84 for treating or preventing malignant cell growth.

The inventions listed as Groups 1-168 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the special technical feature of the first claim is anticipated by WO 9701580A (a copy provided with ISR).

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Groups 1-168 have contain genuses:

1. number of functional domains: two, three, and four.

2. tag: a histidine tag, GST, Staphylococcus protein A, Lex A, a FLAG-tag and MYC-tag.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 3-5, and 27.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the special technical feature of the first claim is anticipated by WO 9701580A.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 703-308-2454. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone number for the organization where this application or proceeding is assigned is 703-305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Misook Yu
November 17, 2003